CENTER FOR GENETICS AND SOCIETY

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To: Amber Christiansen
California Department of Health Services

From: Center for Genetics and Society

Re: Proposed Statewide Guidelines for Human Stem Cell Research for Public Comment

Date: November 28, 2006
Submitted by email

The Center for Genetics and Society (CGS) would like to thank the Department for the opportunity to provide public comment on the proposed statewide guidelines for Human Stem Cell Research.

I. GENERAL COMMENT

Since the DHS guidelines apply to non-CIRM funded research involving human embryonic stem cell research, we appreciate the focus on consistency with CIRM regulations. **However, in the sections of the DHS guidelines that pertain specifically to *oocyte retrieval, the DHS guidelines must be consistent with SB 1260* rather than CIRM guidelines, since SB 1260 was signed into law this year and covers all non-CIRM funded research using human oocytes.**

II. SPECIFIC COMMENTS

§3 Activities Not Permitted

We do not support the elimination of (f) from Section 100030of the CIRM regulations: "The transfer to a uterus of a genetically modified human embryo." It should be clear that such research is unacceptable, even if the language needs further definition. We would support legislation to make that clear, but believe the DHS guidelines should maintain that prohibition in the interim.

§7Additional Requirements for Covered Research Deriving New Human Stem Cell Lines

This section should adopt language directly from SB 1260, Chapter 2 Sections 125330-125355 rather than using language from the CIRM regulations. SB 1260 covers non-CIRM funded research, as do the DHS guidelines, and is now California law.

§11 Record Keeping:

The DHS guidelines must incorporate the data collection and reporting requirements of SB 1260, Chapter 2 Section 125342.

An additional comment on record keeping: data collection is an important aspect of accountability, monitoring, enforcement, and quality. Only with good data collection and review will the state and the public be able to effectively evaluate this new science as it moves forward.

Because of this, we propose the DHS guidelines include several additions to the provisions in SB 1260 regarding data collection:

1. Summaries of proposed research activities that went before the SCRO and the IRB, and whether they were approved.

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2. Policies and procedures adopted by the SCRO.

3. An overview of *all* human stem cell research being done at the institution.

4. An overview of any failures to comply with these standards.

5. A summary of results, both positive and negative, of any non-CIRM-funded research or clinical trial.

6. Any significant adverse reactions in a clinical trial.

7. A disclosure of the personal, professional, and financial interests in biotechnology or biomedical companies of the SCRO members.

8. Health outcomes of oocyte donors resulting from oocyte retrieval, including adverse health reactions resulting from ovarian stimulation.

9. Demographics of oocyte providers used in each stem cell line derived.

These records should be available to the public, with exceptions for the privacy of any patient who may be personally identifiable, or for proprietary intellectual property.

Thank you for your consideration.

Emily Galpern
Project Director on Reproductive Health and Human Rights